To: Thayer, Kris[thayer.kris@epa.gov]
Cc: Bahadori, Tina[Bahadori.Tina@epa.gov]; Yamada, Richard (Yujiro)[yamada.richard@epa.gov]; Morris, Jeff[Morris.Jeff@epa.gov]
From: Beck, Nancy
Sent: Thur 9/14/2017 7:22:46 PM
Subject: RE: IRIS Materials for the 27-28 September SAB-CAAC meeting

Happy to chat more. But again, all the references you cite are from a time when Cochrane was all about RCT. I don't think they ever envisioned what we would be dealing with in the environmental health world, although of course we can all speculate.

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From: Thayer, Kris
Sent: Thursday, September 14, 2017 10:06 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: IRIS Materials for the 27-28 September SAB-CAAC meeting

Thanks Nancy,

We should probably save this for a real-time discussion, but regarding your Cochrane comment about RCT approaches as not fully comparable to our evidence. That is true, but in NO circumstance are numerical scoring systems advocated by Cochrane. I know this because I am involved in several method development collaborations with them to develop approaches for

observational epidemiology studies and pre-clinical/toxicology animal methods. For example, here is the recent tool for assessing observation studies
https://www.ncbi.nlm.nih.gov/pubmed/27733354

My two cents: Hopefully the approach you settle on doesn't dismiss the very strong Cochrane recommendation on numerical scores. Within the "scoring/binning/ranking" options you mention below, you will be on much more solid ground to aim at the "binning/ranking' end of that spectrum. And take care to separate within the tool you use the questions related to reporting, internal validity, and applicability/external validity. You could report these as domains (and articulate your approach to consider domain responses as the basis of binning/ranking rationales) and be at least broadly consistent with the latest and greatest tools used in SR.

Best, - Kris

FYI: Here are some pertinent extracts from the Cochrane handbook, as you can see the rationales provided extend beyond the RTC study design.

The use of scales for assessing quality or risk of bias is explicitly discouraged in Cochrane reviews. While the approach offers appealing simplicity, it is not supported by empirical evidence (Emerson 1990, Schulz 1995b). Calculating a summary score inevitably involves assigning 'weights' to different items in the scale, and it is difficult to justify the weights assigned. Furthermore, scales have been shown to be unreliable assessments of validity (Jüni 1999) and they are less likely to be transparent to users of the review. It is preferable to use simple approaches for assessing validity that can be fully reported (i.e. how each trial was rated on each criterion).

In 1995, Moher and colleagues identified 25 scales and 9 checklists that had been used to assess the validity or 'quality' of randomized trials (Moher 1995, Moher 1996). These scales and checklists included between 3 and 57 items and were found to take from 10 to 45 minutes to complete for each study. Almost all of the items in the instruments were based on suggested or 'generally accepted' criteria that are mentioned in clinical trial textbooks. Many instruments also contained items that were not directly related to internal validity, such as whether a power calculation was done (an item that relates more to the precision of the results) or whether the inclusion and exclusion criteria were clearly described (an item that relates more to applicability than validity). Scales were more likely than checklists to include criteria that do not directly relate to internal validity.

From: Beck, Nancy
Sent: Thursday, September 14, 2017 8:29 AM
To: Thayer, Kris <thayer.kris@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: IRIS Materials for the 27-28 September SAB-CAAC meeting

Kris,

Oct 2 will be a busy day for me as I will be out the Friday before. Hows about Thursday the 5th or Friday the 6th.

I don't find the arguments about scoring compelling for the types of data we are dealing with. The arguments against scoring come from the land where one can easily use meta-analysis to compare randomized control studies—a study design that is pretty much non-existent in the environmental health field. The examples you provide seem to be about scoring in this context (comparing RCT studies only). As you know, our data is much more complex and diverse and when I've spoken to Cochrane folks they agree the approach from the RCT world will not be fully comparable and that we will need new approaches and nothing precludes scoring.

What I do know for certain is that for many decades we have used an approach that talks about considerations and provides asymmetric qualitative write-ups about study designs and strengths and weaknesses. This approach has always fallen short in the eyes of stakeholders, interagency groups, and peer reviewers. Thus we need to find new approaches to be transparent about discussing and comparing and integrating diverse study types of diverse quality. A scoring/binning/ranking approach is something that should be considered in increasing transparency and clarity related to study evaluation—which should include reporting, study quality, internal validity and external validity. The challenge will be to integrate all these findings, incorporating scientific judgment, in a transparent and clear manner.

I'm looping in Venus who assists with scheduling and can hopefully help us find a window on the 5th or 6th.

Thanks!
Nancy

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From: Thayer, Kris
Sent: Thursday, September 14, 2017 5:59 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: IRIS Materials for the 27-28 September SAB-CAAC meeting

Nancy,

Can Monday October 2 work between 11-1?

We can also talk more about the issues with scoring systems like ToxRTool when we meet. In brief, I realize ToxRTool is used by some in the toxicology community but it is not an approach that would fare well in a scientific peer-review by people with experience in SR methods. For a variety of reasons, scoring approaches are discouraged (domain-based approaches are favored; some references are below). In addition, the ToxRTool is mostly aimed at reporting quality, which is a different concept than RoB (internal validity). It also blends aspects of quality

(reporting, internal validity, and applicability into the score) – which is strongly discouraged.

Some references:

From the Cochrane Handbook: the Cochrane Handbook

http://handbook-5-1.cochrane.org/chapter_8/8_3_3_quality_scales_and_cochrane_reviews.htm

https://www.ncbi.nlm.nih.gov/pubmed/12933636

http://www.sciencedirect.com/science/article/pii/S0895435606001284

Quality Scores Are Useless and Potentially Misleading: Reply to "Re: A Critical Look at Some Popular Analytic Methods"

http://jamanetwork.com/journals/jama/fullarticle/191652

From: Beck, Nancy
Sent: Wednesday, September 13, 2017 8:18 AM
To: Thayer, Kris <thayer.kris@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: IRIS Materials for the 27-28 September SAB-CAAC meeting

Kris,

Happy to have a conservation when you are ready and available.

Thanks,
Nancy

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Sent: Wednesday, September 13, 2017 4:11 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: IRIS Materials for the 27-28 September SAB-CAAC meeting

Thanks for the questions Nancy – I've added some brief comments below. Some of these points are probably best discussed in real-time. We are swamped until after the September SAB CAAC but perhaps we can find time to meet in October?

From: Beck, Nancy
Sent: Tuesday, September 12, 2017 9:37 PM
To: Thayer, Kris <thayer.kris@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>
Subject: RE: IRIS Materials for the 27-28 September SAB-CAAC meeting

Kris,

Thanks for sharing. I've only skimmed the documents very quickly but I do have a few simple

questions:

•□□□□□□□ Its still not clear to me what you mean by a portfolio approach. Is it that you may simply do a RfC before or separate from a RfD or cancer value? That's just one example of the portfolio. Is the basic framework for developing each endpoint going to remain the same and will you continue to use the RfV's and the cancer values as the endpoints of interest? It isn't clear to me how this moves us away from "one size fits all." For instance in OPPT we rely on a POD and don't apply UF's as IRIS does, so we don't really need IRIS to develop RfV's for us. We are fine to provide OPPT with PODs only, but we should discuss how this will best work in practice, in particular for assessments where OPPT isn't the only EPA Office/Program with an interest in the assessment. Tina and I have some options in mind and would welcome the opportunity to discuss.

•□□□□□□□ In your attachment A figure for the IAP, it would be useful to explain to us where you plan to have internal EPA review. After which steps? The draft IAPs went through internal agency review over the summer. Beyond the draft IAP stage, we are working within the existing internal EPA review processes. We have a slide on this for the upcoming September 20 STPC meeting.

•□□□□□□□ While the scoping summary table shows what programs may have an interest in a value, where can we find information on how IRIS prioritizes which chemicals to review? Is IRIS planning to do a prioritization exercise anytime soon within the Agency? For example, there are 189 HAPs and not many of them have IRIS values, how will you decide which HAPs to review? It seems the need for them would be consistent under 112d. This is a good topic for a fuller discussion but in short, our prioritization is based on standing commitments (such as multi-year agenda chemicals – but confirming they meet current administration priorities), finding capacity to meet emerging needs of the agency (especially for small evidence-base topics), and staff resources.

•□□□□□□□ I'm not sure tables/visuals that show the number of studies available for each endpoint are on their own useful. Doesn't the quality of those studies matter? Is this just a screening tool to help focus the evaluation? Yes, the number of study inventories are used as a screening tool to help us get a sense of level of effort, nature of the evidence (e.g., epi, animal, in vitro), and type of expertise that will likely be required to conduct the assessment

•□□□□□□□ In the specific aims, looking at EB as an example, it says you will evaluate risk of bias and sensitivity. How does this evaluation compare to something like the ToxRTool which is used internationally (or Klimisch which was used quite a bit by OPPT for our HPV program), to evaluate the study quality of toxicological data? This is probably a good topic for a briefing, but in short the IRIS approach includes a reporting quality domain that covers much of the ToxRTool content, but also has other domains that are more widely used in the SR community. Applicability or relevance of the study to the assessment question can be addressed as part of adherence to the PECO-statement. Obviously, we save resources if we don't spend time doing study quality assessment or data extraction on studies that are not really relevant to the assessment needs. We also consider applicability as part of our structured framework for assessing weight of evidence. Consistent with standards in systematic review, we do try to be

transparent in separating out considerations related to risk of bias (internal validity) and applicability.

•□□□□□□□ You note that studies with critical deficiencies will be considered uninformative, but what about other gradations of study quality? The discussion on synthesis makes no mention of giving preference to higher quality studies over lower quality studies. This is important to us as TSCA requires us to consider quality when integrating information. Again, a good topic of a briefing. We explicitly consider the other gradations of study quality as part of our evidence synthesis, which we are trying to make more consistent and transparent via use of evidence profile tables. I think for future draft IAPs we can consider elaborating on that specific aim to give the reader a sense of factors we consider during the process of evidence synthesis. A fuller description of the evidence synthesis process is presented in chemical-specific protocols and the IRIS Handbook.

•□□□□□□□ In the PECO statement, looking at EB, under exposure, there really doesn't seem to be any consideration of environmentally relevant doses. Is IRIS continuing to focus on any dose from animal studies and mechanistic studies without trying to give a preference to doses that may be within the range of typical human exposures. It really depends on the Agency scoping need and also the chemical in question. For example, if the Agency scoping need isn't already targeted to a certain dose range, then we may need to consider the size and nature of the evidence base during our initial problem formulation….e.g., when there are a lot of studies then we may opt to focus on those that test lower doses….or perhaps limit the SR to focus to health outcomes that are associated with lower dose effects. I'm very curious how you are approaching this for TSCA, in particular as you move into full-text review screening criteria and subsequent implementation of SR.

Thanks again for sharing the documents.

Nancy

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Sent: Tuesday, September 12, 2017 5:56 AM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: FW: IRIS Materials for the 27-28 September SAB-CAAC meeting

Nancy,

Good morning. Please find attached the draft IRIS Assessment Plans (IAPs) for the upcoming SAB CAAC meeting (September 27-28). For context, the draft IAPs do NOT represent the last public outreach during the course of preparing a draft assessment. During the September meeting, we will spend a significant amount of time discussing additional transparency steps in IRIS process for implementing SR.

We are happy to tell you more about our processes if you'd like. During our previous meetings, we really focused on *how* we are implementing SR within IRIS (e.g., methods) but we have not yet shared with you approaches for making it pragmatic or steps for promoting transparency during the course of the assessment.

Please let us know if you have any questions or would like to meet and discuss,

Kris

Kristina Thayer, Ph.D.

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Subject: IRIS Materials for the 27-28 September SAB-CAAC meeting

Hello Everyone,

Attached, you will find the IRIS background documents for the upcoming SAB Chemical Assessment Advisory Committee (SAB-CAAC), scheduled for 27-28 September. The "IAP Background" provides an overview of the expectations for this meeting. The other three documents are IRIS Assessment Plans (for nitrate/nitrite, chloroform, and ethylbenzene) that

demonstrate how systematic review is being formally integrated into the existing scoping and problem formulation step of IRIS. Many of you were involved in and helped in shaping these efforts over the past few months – and we thank you! More information about the SAB meeting can be found:
https://yosemite.epa.gov/sab/sabproduct.nsf//MeetingCalBOARD/B993D2C54053CD9A8525817D005FD1E2?

Please let us know if you have any questions or need additional information.

Tina

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Tina Bahadori, Sc.D.

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